

REMARKS

I. STATUS OF THE CLAIMS

After entering this amendment, Claims 36-42, 44-64, and 66-69 will be pending in this application. Claim 36 is amended herein to incorporate subject matter canceled from Claim 40 and to recite that the compound of formula (I) is not one of quinuclidin-3-yl benzo[d][1,3]dioxol-5-ylmethyl(phenyl)carbamate or quinuclidin-3-yl (2,3-dihydrobenzo[b][1,4]dioxin-6-yl)methyl(m-tolyl)carbamate. Support for this amendment can be found in the as-filed Specification at page 4, lines 21-23. Claim 40 has also been amended to correct a typographical error. Claim 37 is amended herein to incorporate the subject matter of Claim 43, which is herein canceled without prejudice or disclaimer. Claims 38 is amended herein to correct typographical errors. Claims 65 and 70-79 are herein canceled without prejudice or disclaimer. No new matter has been added by these amendments.

In the Office Action at 2, the Examiner states that "Claims 36-69 are pending." This is incorrect. Claims 36-79 were pending in this application before entry of the amendments presented herein. Claims 70-79 were added in the Supplemental Preliminary Amendment filed in the instant application on July 11, 2006, and are herein canceled. Clarification of the record is respectfully requested.

II. PERFECTION OF PRIORITY

In the Office Action, the Examiner states that “[t]his application was filed on 09/19/2005, which is a 371 of PCT/EP03/06472, filed on 06/18/2003, which claims benefit of priority document SPAIN P200201439, filed on 06/21/2002. The claimed benefit of priority date is denied. There is no certified translation of the priority document. The filing date of the instant application is 06/18/2003.” Office Action at 2. To perfect their claim for priority, Applicants submit concurrently with this Amendment and Response a certified English translation of Spanish Application No. P200201439.

III. REJECTION UNDER 35 USC § 112, SECOND PARAGRAPH

The Examiner rejects Claims 6 and 15 under 35 USC § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” *Id.* However, Claims 1-35 have been canceled. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Examiner also rejects Claim 65 alleging that “the claim is vague and indefinite.” *Id.* While Applicants respectfully disagree, they submit that the rejection has been rendered moot by the cancellation of Claim 65 in the amendment herein presented.

IV. REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH

The Examiner rejects Claims 65-69 under 35 USC § 112, first paragraph, as allegedly “failing to comply with the enablement requirement because the specification does not enable the instant compound to alter the gene expression and therefore to treat any and all known or unknown diseases.” *Id.* at 3. The Examiner further asserts that “it is not seen where the instant claim 65-69, for treating diseases by antagonism of M3 muscarinic receptor is effective, have been enabled by the instant specification.” *Id.* at 6. Finally, the Examiner alleges that “the breadth of the claims is drawn to method for treating a subject afflicted with a pathological condition or disease susceptible to amelioration by antagonism of M3 muscarinic receptors using the compounds of claim 36.” *Id.* at 5-6. Applicants respectfully traverse the rejection under § 112, first paragraph, for at least the following reasons.

With regard to Claim 65, Applicants submit that the rejection has been rendered moot by the cancellation of Claim 65 in the amendment herein presented. Accordingly, Applicants respectfully request that this rejection be withdrawn.

With regard to Claims 68 and 69, Applicants respectfully submit that these claims are drawn to combination products, not methods, as alleged by the Examiner. Claim 68 recites in part a “combination product comprising, (i) at least one first compound of Claim 36; and (ii) at least one second compound effective in the treatment of at least one pathological condition chosen from respiratory, urological, and gastrointestinal disease or disorder.” Claim 69 recites in part a “combination product comprising, (i) at

least one first compound of Claim 36; and (ii) at least one second compound chosen from a β_2 agonist, steroid, antiallergic drug, phosphodiesterase IV inhibitor, and a leukotriene D4 (LTD4) antagonist." While Applicants disagree with the Examiner's characterization of the present specification, it is not seen how the Examiner's statements regarding gene expression, disease treatment, or the role of M3 muscarinic receptors are relevant to Claims 68 and 69, which are drawn to products. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 68 and 69 under § 112, first paragraph.

With regard to Claims 66 and 67, Applicants note that Claim 66 is drawn to "a method for treating a subject afflicted with **a pathological condition or disease susceptible to amelioration by antagonism of M3 muscarinic receptors**, comprising administering to said subject an effective amount of at least one compound of Claim 36." (Emphasis added.) That is, only treatment of those pathological conditions or diseases that are susceptible to amelioration by antagonism of M3 muscarinic receptors is claimed. By definition, a pathological condition or disease that is susceptible to amelioration by antagonism of M3 muscarinic receptors can be treated by administration of an M3 muscarinic receptor.

In the Office Action at 5, the Examiner states that "applicants have shown [the] nexus between the instant compounds and muscarinic receptors" but alleges that "applicant provides no guidance or examples for how muscarinic receptor could treat any and all known or unknown diseases. There are no examples in the instant specification showing that the instant compounds can treat any diseases from

respiratory, urological, and gastrointestinal disease or disorder.” Applicants respectfully submit that there is considerable literature regarding the role of M3 muscarinic receptor antagonists in the treatment of diseases characterized by an increased parasympathetic tone, by excessive glandular secretion, or by smooth muscle contraction, and that examples of this kind of diseases or disorders include, but are not limited to, respiratory disorders, urological disorders, and gastrointestinal disorders. For example, *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, which is of record in the instant application, states that “[t]he therapeutic uses of muscarinic receptor antagonists include treatment of gastrointestinal and urinary tract disorders, specific respiratory conditions” (Chapter 7, page 155, *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 10th edition; internal citations omitted).

Because treatment of a number of pathological conditions or diseases with M3 muscarinic receptor antagonists has been well documented and described in the art, instant claims 66 and 67, directed to those pathological conditions or diseases that are susceptible to amelioration by antagonism of M3 muscarinic receptors, are enabled. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 66 and 67 under § 112, first paragraph.

V. REJECTION UNDER 35 USC § 102

The Examiner rejects claims 36-64 under 35 U.S.C. § 102(a,e) as allegedly being anticipated by WO 03/053966 by Catena Ruiz et al. (“*Catena Ruiz*”). Office Action at 7.

Applicants note *Catena Ruiz* is a WIPO publication of the English-language International Application PCT/EP02/14470, filed on December 18, 2002, and published on July 3, 2003. Accordingly, the earliest possible date of this reference under § 102(e) is December 18, 2002. Applicants respectfully remind the Examiner that the instant application is a § 371 of PCT/EP03/06472 filed June 18, 2003, which claims priority, herein perfected, to ES P200201439, filed June 21, 2002. Therefore, the instant application has an effective filing date of June 21, 2002, and, consequently, *Catena Ruiz* is not available as a reference under § 102(e) against the present claims. *Catena Ruiz* is also unavailable as a reference under § 102(a). Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Examiner also rejects claims 36-64 under 35 U.S.C. § 102(a,e) as allegedly being anticipated by WO 02/051841 by Buil Albero et al. ("*Buil Albero*"). Office Action at 7. 35 U.S.C. § 102(a) establishes that a person shall be entitled to a patent unless "the invention was known or used **by others** in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent" (emphasis added). Furthermore, M.P.E.P. 2132.III states that "[t]he term 'others' in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be 'by others.' This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use." With regard to 35 U.S.C. § 102(e), M.P.E.P. 706.02(f) states that "[i]n order to apply a reference under 35 U.S.C. 102(e),

the inventive entity of the application must be different than that of the reference.

Note that, where there are joint inventors, only one inventor needs to be different for the inventive entities to be different and a rejection under 35 U.S.C. 102(e) is applicable even if there are some inventors in common between the application and the reference” (emphasis added).

Buil Albero lists as inventors Maria Antonia Buil Albero, Maria Dolors Fernandez Forner, and Maria Prat Quinones. The present application lists as inventors Maria Prat Quinones, Maria Antonia Buil Albero, and Maria Dolors Fernandez Forner. Thus, Applicants respectfully submit that *Buil Albero* is not available as a reference under § 102(a), nor is it available as a reference under § 102(e), for at least the reason that the inventive entity of the present application is not different than that of *Buil Albero*. Accordingly, Applicants respectfully request that the § 102 rejection over *Buil Albero* be withdrawn.

Finally, the Examiner rejects claims 36-64 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02/00652 by Farrerons Gallemi et al. (“*Farrerons Gallemi*”). Office Action at 8. In light of the amendments herein presented, Applicants submit that *Farrerons Gallemi* does not disclose compounds according to independent Claim 36 or according to independent Claim 37 and thus does not anticipate the pending claims. Accordingly, Applicants respectfully request that the § 102 rejection over *Farrerons Gallemi* be withdrawn.

VI. DOUBLE PATENTING REJECTION

In the Office Action at 8-9, the Examiner rejects Claims 36-64 “under the judicially created doctrine obviousness-type double patenting” over Claims 1-19 of U.S. Patent No. 7,208,501 to Buil Albero et al. (“the ‘501 patent”). In making this rejection, the Examiner asserts that “Buil Albero et al. claimed identical compounds and salts of the compounds in claims 1-19 as the instant claims 36-64” and that “the scope of both sets of claims overlaps most significantly with each other.” Office Action at 8. The Office further argues that the claims in the issued patent are “fully embraced by the instant claims.” *Id.*

Applicants respectfully request that this rejection be held in abeyance until the Examiner has indicated that allowable subject matter is present in the application. Applicants will consider filing a Terminal Disclaimer at that time.

CONCLUSION

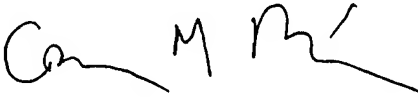
In view of the above amendments and remarks, Applicants respectfully request reconsideration of this application, and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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